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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,354	01/14/2004	Bradley P. Glassman	025562.0012-US01	3208
26853	7590	05/10/2006	EXAMINER	
COVINGTON & BURLING ATTN: PATENT DOCKETING 1201 PENNSYLVANIA AVENUE, N.W. WASHINGTON, DC 20004-2401				SHEIKH, HUMERA N
ART UNIT		PAPER NUMBER		
		1615		

DATE MAILED: 05/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/756,354	GLASSMAN ET AL.
	Examiner	Art Unit
	Humera N. Sheikh	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 28 October 2005.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-13 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-13 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

*Humera N. Sheikh*  
 HUMERA N. SHEIKH  
 PATENT EXAMINER  
 TC-1600

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date 10/28/05.

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

**Status of the Application**

Receipt of the Amendment after Final Office Action, Applicant's Arguments/Remarks and the Information Disclosure Statement (IDS), all filed 10/28/05 is acknowledged.

Applicant's request for reconsideration of the finality of the rejection of the last Office action (filed 7/28/05) is persuasive and, therefore, the finality of that action is withdrawn. The following are the new grounds of rejection:

Claims 1-13 are pending in this action. Claims 1-13 are rejected.

***New Matter***

The amendment filed 10/28/05 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure, is as follows:

Applicant fails to provide support for “urea as the sole active antifungal ingredient” in the Specification.

Applicant is required to cancel the new matter in the reply to this Office Action.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun *et al.* (WO 96/19186) in view of Chodosh (U.S. Pat. No. 5,661,170).**

*Sun et al.* ('186) teach a method of treating fungal diseases in nails comprising administering to the nail a composition comprising: a) urea in an amount from about 1% to about 50%; b) an antioxidant consisting of 10.0% N-acetyl-1-cysteine; and c) mineral oil in amounts of 3.0% (see Abstract; (page 3, lines 13-24); (page 7 lines 6-20); (pg. 8, lines 16-31); (pg. 10, lines 41-46); Tables at pages 14-21 and Formulations D-K at pages 29-31.

*Sun et al.* teach antioxidants such as N-acetyl-1-cysteine. *Sun et al.* do not teach Vitamin E.

**Chodosh** ('170) teaches antimicrobial compositions and methods for using said compositions for treating bacterial infections of the nails or for treating onychomycosis, comprising Vitamin E, which is an antioxidant known for protecting cells from oxidation. The Vitamin E can function as a moisturizer or humectant (see reference column 2, lines 48-59); (col. 5, lines 47-67). The compositions can be applied as a gel, lotion, ointment, salve, paste or cleanser (col. 7, lines 15-43).

Both references teach a composition comprising urea, an antioxidant and excipients, which are known for treating onychomycosis or bacterial infections of the nails. It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose (See *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980)).

One having ordinary skill in the art would have been motivated to prepare a third composition by including Vitamin E in the Sun *et al.* document, because a third composition can be used for the same purpose for treating bacterial infections or fungal diseases of the nails, and one would expect to achieve similar beneficial results. It would therefore have been obvious to combine the teachings of Sun *et al.* within Chodosh. The expected result would be a method for treating onychomycosis comprising applying to nail(s), a composition comprised of urea, Vitamin E and excipient(s).

***Response to Arguments***

Applicant's arguments filed 10/28/05 have been fully considered but they are not persuasive. Applicant argued, "Urea is not even listed among antifungal drugs that can be used in the invention, described in the Sun PCT (page 7, lined 35 to page 8, line 5). Nowhere in the Sun PCT is there a recognition that urea can be an effective antifungal ingredient, much less that it can be the sole active antifungal ingredient in a composition effective for treating onychomycosis. Thus, in contrast to the claimed invention, the Sun PCT does not teach or suggest urea as the sole active antifungal ingredient in a composition effective for treating onychomycosis. The language 'urea as the sole active antifungal ingredient excludes itraconazole, ketoconazole, miconazole nitrate and any of the other antifungal drugs listed in the Sun PCT from compositions employed in methods of the present invention.

The Chodosh patent also does not teach or suggest using urea as the sole active antifungal ingredient in effectively treating onychomycosis. Nowhere in the Chodosh patent is there any mention of 'urea' as opposed to the preservatives 'imidazolidinyl urea' and 'diazolidinyl urea', much less any mention of urea as an effective antifungal ingredient. Thus, the independent claims patentably distinguish the present invention over the Sun and Chodosh documents, whether those documents are taken individually, or in combination. Neither the Sun PCT nor the Chodosh patent would have caused one of ordinary skill in the art to think that urea could be used as the sole active antifungal ingredient in a composition therapeutically effective for the treatment of onychomycosis."

Applicant's arguments have been fully considered but they were not persuasive. Applicant's argument that "Nowhere in the Sun PCT is there a recognition that urea can be an effective antifungal ingredient, much less that it can be the sole active antifungal ingredient in a composition effective for treating onychomycosis" was not persuasive since Sun et al. vividly teach the use of 'urea' for effectively treating nail fungal diseases, especially onychomycosis. Since the prior art clearly teaches the use of the same component, the beneficial results and properties imparted by that particular component, would also be the same. The particular component in this case being urea. Moreover, the Examiner notes that it is not necessary that the prior art teach each and every property which accrues from a particular ingredient, but merely that the prior art teach the same component for a similar field of endeavor is sufficient. Regarding Applicant's argument that "Sun et al. do not teach urea as the sole active antifungal ingredient in a composition effective for treating onychomycosis", the Examiner points out that there is lack of support for the limitation of urea as the sole active antifungal ingredient. Thus, the presence of additional active ingredients is permissible in the presently claimed invention. Furthermore, Applicants have not demonstrated that the inclusion of additional active components in the prior art references, would be detrimental or adversary if utilized in the invention claimed herein. It is the position of the Examiner that the prior art explicitly teaches a similar method for treating nail fungal conditions, such as onychomycosis, by incorporating similar components that are used for the same field of endeavor as that desired by Applicant.

Applicant's argument that "The Chodosh patent also does not teach or suggest using urea as the sole active antifungal ingredient in effectively treating onychomycosis" has been fully

considered but was not found persuasive. The Chodosh patent was relied upon for the teaching of the use of vitamin E in antimicrobial and antifungal compositions and relied upon to demonstrate that it is well known in the art to employ antioxidants, such as vitamin E, to effectively treat antimicrobial or antifungal conditions, such as onychomycosis, to a subject in need thereof. The Chodosh patent was not relied upon for the teaching of 'urea' since the Sun et al. PCT initially meets this requirement of employing urea in antifungal formulations and methods. Thus, since Chodosh vividly teaches the incorporation of vitamin E in antifungal compositions and methods for treating thereof and teaches that beneficial results are attained therewith, ample motivation has been provided by the prior art. It remains the position of the Examiner that Applicants have not demonstrated any unusual and/or unexpected results through the instantly claimed combination of ingredients. The prior art explicitly teaches similar methods of treating onychomycosis by topical application of urea, antioxidants (*i.e.*, vitamin E) and excipients (*i.e.*, mineral oil).

Hence, given the teachings of the prior art delineated above, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

#### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh

Patent Examiner

Art Unit 1615

May 08, 2006

*hns*

*Humera N. Sheikh*  
TC-1600